

REMARKS

This amendment is filed along with a Request for Continued Examination.

This application is amended in a manner believed to place it in condition for allowance at the time of the next Official Action.

Claims 32-37, 39-43, 45-48, 50, 53-58 are amended.

Support for the amendment to the claims may be found, for example, in the paragraph bridging pages 3 and 4, item 6 of page 11, and item 15 of page 13.

Claims 32-58 remain pending in the application.

The Official Action rejects claims 43 under 35 U.S.C. 112, first paragraph, for not complying with the written description requirement. This rejection is respectfully traversed.

The position of the Official Action is that there is no written support for auxiliaries "and mixtures thereof". However, specification page 11, line 1-2, discloses "[t]he solution with the polyurethane content to be delivered to the site of the intervention may contain one or more auxiliary materials commonly used in the field." (Emphasis added.) Thus, there is written support for "mixtures thereof" in claim 43.

Therefore, withdrawal of the rejection is respectfully requested.

Claims 32-36, 40-41, 43, 45-50, 54-55 and 57-58 are rejected under 35 USC §102(b) as being anticipated by GARIBALDI et al. U.S. 6,296,604 (GARIBALDI). This rejection is respectfully traversed.

GARIBALDI is offered for teaching a biocompatible composition comprised of a precipitating polymer such as polyurethane dissolved in a solvent such as DMSO or EtOH, an adhesive, and a magnetic embolic agent.

However, the correct categorization of GARIBALDI is a magnetic embolic agent that includes a polymer, a solvent, an adhesive to stick to the blood vessel wall, and a great amount of magnetic material so that the magnetic embolic agent moves in response to a magnetic field. See, e.g., the abstract, the paragraph bridging columns 3 and 4, and column 4, lines 24-33.

The compositions and kits of independent claims 32 and 46 comprise components to be delivered to a vascular cavity. These components consist essentially of i) a sufficient amount of a polyurethane to fill a vascular cavity and ii) a sufficient amount of solvent or solvent mixture to dissolve the polyurethane, and the components do not stick to blood vessel walls. The optional auxiliary materials provide contrastive properties for monitoring the position of the components, without materially affecting the basic characteristics of the components to be delivered to a vascular cavity.

Thus, GARIBALDI requires at least two "components" that are excluded by the claimed invention: an adhesive and a magnetic material.

With respect to the magnetic materials in particular, the optional auxiliary materials of the claimed invention may include paramagnetic materials. Paramagnetic materials material, however, are distinct from magnetic materials, as paramagnetic materials do not maintain magnetic properties after exposure to a magnetic field, i.e., as recognized by GARIBALDI in column 4, lines 13-18. Thus, the large quantity of magnetic materials required by GARIBALDI would materially affect the basic characteristics of components of the claimed invention, and are not included in the components in the claimed invention.

As GARIBALDI requires materials that would affect the basic characteristics of the components and that are excluded from the claimed invention, GARIBALDI cannot anticipate independent claims 32 and 46, and the dependent claims 33-36, 40, 41, 43, 45, 47-50, 54, 55, 57 and 58.

Therefore, withdrawal of the rejection is respectfully requested.

Claims 32-34, 37-42, 44, 46-48 and 51-56 are rejected under 35 USC §102(b) as being anticipated by MARINOVIC EP 0 280 451(MARINOVIC). This rejection is respectfully traversed.

MARINOVIC is offered for teaching polyurethanes that are used as space filling adhesive sealants in surgery, and the polyurethanes are prepared by mixing prepolymers of diisocyanate and polyols. The position of the Official Action is that polyetherurethane urea polymer is a polyurethane polymer, the aqueous solution containing a chain extender is a solvent containing an auxiliary agent, and the molecular weight of the polymer is 1,950-15,000.

However, MARINOVIC fails to anticipate the independent claims 32 and 46 for at least three reasons:

I. Neither the polymer nor the prepolymer is polyurethane.

MARINOVIC discloses polyETHERurethane prepolymers and polyETHERurethane urea polymers. The abstract describes the preparation of polyetherurethane urea polymers by mixing purified diisocyanate polyetherurethane prepolymers with an aqueous solution of an amino, ureido, or hydroxyl substituted amine or a like substituted alpha-amino acid, and the polymers are used as a space filling adhesive sealant in surgery.

The polyetherurethane prepolymers have a polyether core and two isocyanate terminal groups, i.e., as described on page 4 of MARINOVIC. That is, there are two formed urethane groups (i.e. -NHCOO-) connected to -Z-NCO- groups at the ends of the polyether core.

If a diisocyanate polyetherurethane prepolymer is reacted with a diol, then a polyurethane polymer is obtained. However, MARINOVIC reacts the prepolymer with a chain extending compound having a reactive NH₂ group. As a result, polyetherurethane urea type polymers are formed, where -NH-CO-NH-(urlyene) groups ensure crosslinking to cause solidification/hardening.

Thus, MARINOVIC fails to disclose polyurethane.

II. Neither the polymer nor prepolymer is soluble in the solvent and solidifies upon separation from the solvent.

MARINOVIC starts with a liquid polyetherurethane prepolymer, i.e., as described in lines 30-46 on page 5 of MARINOVIC. This liquid prepolymer requires the addition of a solution, with a chain extender, to solidify/harden into the polyetherurethane urea polymer. Thus, the prepolymer solidifies upon addition to the solution, not separation from a solvent.

III. The polymer would stick to a blood vessel wall.

The polyetherurethane urea polymers of MARINOVIC are described as an adhesive sealant. Thus, MARINOVIC fails to teach components that do not stick to the blood vessel wall.

Therefore, in view of the above, MARINOVIC cannot anticipate independent claims 32 and 46, and dependent claims 33, 34, 37-42, 44, 47, 48 and 51-56, and withdrawal of the rejection is respectfully requested.

Claims 32-58 are rejected under 35 USC §103(a) as being obvious over GARIBALDI in view of MARINOVIC. This rejection is respectfully traversed.

GARIBALDI is offered for the reasons discussed above. The Official Action recognizes that GARIBALDI does not disclose the exact diisocyanate and polyol monomers used to produce the polymer and the molecular weight of the polyurethanes.

MARINOVIC is offered for the reasons discussed above and for teaching polyurethanes having the claimed molecular weight formed by the condensation products, already known as an adhesive sealant, of the claimed diisocyanates and polyols. Additionally, the Official Action offers MARINOVIC for teaching that the adhesives are non-toxic, rubbery, not brittle, and capable of being sculpted.

The position of the Official Action is that it would have been obvious to combine the publications because the combination would result in polyurethanes for the purpose of GARIBALDI produced by the monomers of MARINOVIC of a particular molecular weight to provide a desirable viscosity that is rubbery when applied, not brittle, and non-toxic, which are desirable traits for a surgical adhesive.

However, the proposed combination fails to teach features of independent claims 32 and 46, such as, (1) components consisting essentially of polyurethane and a solvent or solvent mixture, (2) polyurethane that is soluble in the solvent and

solidifies upon separation from the solvent, and (3) components that do not stick to the blood vessel walls.

As discussed previously the overall composition of GARIBALDI requires magnetic particles in a great amount and an adhesive, i.e., components which would material affect the basic characteristics of the components of the claimed invention, and MARINOVIC discloses a liquid polyetherurethane prepolymer, which solidifies upon addition to a solvent to form an adhesive polyetherurethane urea polymer. Thus, at best, the combination teaches an adhesive and magnetic composition comprising magnetic particles and liquid polyetherurethane prepolymer that solidifies upon addition to a solvent and auxiliary material.

Therefore, the proposed combination fails to render obvious independent claims 32 and 46, and dependent claims 33-45 and 47-58, and withdrawal of the rejection is respectfully requested.

In view of the above, applicant believes that the present application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



Robert Madsen Reg. No. 58,543
745 South 23rd Street
Arlington, VA 22202
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

RAM/fb